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EXAMINER

RIMELL, SAMUEL G

ART UNIT

PAPER NUMBER

2175

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,774

Applicant(s)

KAGAN, RON M.

Examiner

Sam Rimell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.


SAM RIMELL
PRIMARY EXAMINER

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____

Claims 3, 11, 19 and 27 are objected to since these claims end in a semi-colon instead of a period. A claim is supposed to be one single complete sentence, and thus must end in a period. Correction is required.

Claims 1-7 are objected to for making reference to non-existent claims. Claims A1 through A5 do not exist in the record, so the reference to such claims is improper. It is also noted that claim dependencies should not include alphabetical letters, and that claims should not be numbered with alphabetical letters.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 8-11, 14, 16-19, 22, 24-27 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Jeffreys (U.S. Patent 5,811,235).

Claim 1: FIG. 5C illustrates rows of diploid MVR codes extending for at least 50 repeat units. The entire set of all diploid codes for all ethnicities is a sequence database. As seen in FIG. 5C, patient sample sequences, such as “English” and “Mormon” are compared other sequences in the sequence database. The closest matches are determined, as seen in the upper four lines of FIG. 5C. A normalized matching score, in the form of a series of “x”s are produced. The normalized matching score is the number of “x”s that are produced when comparing the lines of repeat units.

Claim 2: FIG. 6B illustrates a match probability for each unit along the horizontal line of repeat units. The match probability is the confidence level. The confidence thresholds are the range of probability values displayed in the chart of FIG. 6B.

Claim 3: FIG. 5C illustrates the closest matches in the first four rows. The profile manager is the programming that creates the display of FIG. 5C, which is also a report.

Claim 6: The sample sequence is derived from DNA (col. 6, line 22).

Claim 8: FIG. 5C illustrates received patient sample sequences of diploid MVR codes that extend for 50 repeat units. For example, the first line “English” is a received patient sample sequence. As seen in FIG. 5C these are compared to an overall database of sample sequences derived from multiple ethnicities, such as Japanese and French (col. 18, lines 21-29). The closest matches to the sample sequence are determined. For example, the closest match to “English” is “Mormon” and “Japanese”. The normalized matching score is the number of “x”s produced when making the comparison. The closest match has the least number of “x”s.

Claim 9: See remarks for claim 2.

Claim 10: FIG. 6B illustrates a match probability for each repeat unit. The confidence level is the match probability. The confidence thresholds are the range of probability values displayed in FIG. 6B.

Claim 11: See remarks for claim 3.

Claim 14: See remarks for claim 6.

Claim 16: See remarks for claim 8.

Claim 17: See remarks for claim 2.

Claim 18: See remarks for claim 10.

Claim 19: See remarks for claim 3.

Claim 22: See remarks for claim 6.

Claim 24: See remarks for claim 8.

Claim 25: See remarks for claim 2.

Claim 26: See remarks for claim 10.

Claim 27: See remarks for claim 3.

Claim 30: See remarks for claim 6.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5, 7, 12, 13, 15, 20, 21, 23, 28, 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeffreys (U.S. Patent 5,811,235) in view of Official Notice.

Claim 4: Col. 6, lines 22-24 of Jeffreys teaches that the DNA can derive from any animal species but preferably humans. Jeffreys differs in that it does not teach the DNA deriving specifically from human viruses. However, examiner takes Official Notice that DNA exists in human viruses. Since Jeffreys relies on DNA derived from the human species and DNA is well known to exist in viruses in the human species, it would have been obvious to one of ordinary skill in the art to derive the DNA of Jeffries from human viruses as one of many well known sources for DNA that reside in the human body.

Claim 5: Col. 6, lines 22-24 of Jeffreys teaches that DNA can derive from any animal species, but preferably humans. Jeffreys differs in that it does not teach DNA deriving

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specifically from human HIV viruses. However, examiner takes Official Notice that DNA exists in the human HIV virus. Since Jeffreys relies on DNA derived from the human species and DNA is well known to exist in the human HIV virus, it would have been obvious to one of ordinary skill in the art to derive the DNA of Jeffreys from human HIV viruses as one of many well known sources of DNA that reside in the human body.

Claim 7: FIG. 6B of Jeffreys already teaches measures of match probability for each repeat unit along the horizontal axis of repeat units in FIG. 5C. However, Jeffreys does not teach the confidence threshold (the range of values in FIG. 6B) as being set at a particularly desired level, such as three standard deviations from an average normalized score. Examiner takes Official Notice that the Standard Deviations for the sets of normalized scores can be calculated, particularly since the standard deviation is standard algorithm and can be readily determined.. Setting the confidence threshold at three standard deviations would have been obvious to one of ordinary skill in the art as a choice of design for the range of values shown in FIG. 6B.

Claim 12: See remarks for claim 4.

Claim 13: See remarks for claim 5.

Claim 15: See remarks for claim 7.

Claim 20: See remarks for claim 4.

Claim 21: See remarks for claim 5.

Claim 23: See remarks for claim 7.

Claim 28: See remarks for claim 4.

Claim 29: See remarks for claim 5.

Claim 31: See remarks for claim 7.

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Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (703) 306-5626.

A handwritten signature in black ink, appearing to read 'S. Rimell', written in a cursive style.

Sam Rimell
Primary Examiner
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